Case Studies in Engineering Failure Analysis 4 (2015) 64–75

Contents lists available at ScienceDirect

Case Studies in Engineering Failure Analysis

journal homepage: www.elsevier.com/locate/csefa

Case study

Pedicle screw rupture: A case study

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ARTICLE INFO

Article history:
Received 4 August 2015
Received in revised form 9 September 2015
Accepted 21 September 2015
Available online 28 September 2015

Keywords:
Lumbar prosthetics
Screws and connecting bars
Titanium Ti6Al4V alloy

ABSTRACT

In this work we present a technical description related to the rupture of a titanium alloy pedicle screw and connecting bar implanted in dorsal vertebras of a patient. Only metallurgical facts are described, with no attempt to identify any imperfections in the clinical aspects related to the rupture. The results described here are based on extensive analysis of the broken materials in a material sciences specialized laboratory. Excluding an incorrect prosthesis implantation in the surgical procedure and a possible low bone density, an information not available to the research team, with high probability the rupture of metallic pieces used in the prosthetic implant, was produced by the low fatigue resistance resulting by an improper machining process and excessive bending of the connecting bar prior to implant.

1. Introduction

The person involved in this clinical case, named here simply as the "patient", was suffering with intense pains in the lumbar region of his dorsal spine. Clinical treatments were used with no results, resulting in the surgical action in order to insert a prosthetics linking two adjacent vertebras, so as to eliminate the effect of a broken connection between these vertebras. After about six months from the surgical intervention, the patient was suffering again by intense pains in the region where the prosthetic was implanted. X-rays and Tomography revealed the rupture of a screw and attached connecting bar. A new surgical intervention was done to substitute the prosthetic. The patient sued the company responsible for the prosthetic material, claiming a certain amount for both physical and psychological discomfort.

Some articles have related features of surgeries and instrumentation used.

Intravertebral and intrapedicular pedicle screw bending moments were studied by [1] as a function of sagittal insertion angle. The influence of various parameters on the failure of fixation systems due to the pull-out phenomenon of the fixation screws was explored by [2] through a finite element model of the human lumbar vertebral bone and of the transpedicular fixation screw with the design simulation based on the main characteristics of commercial fixation pedicle screws.

The goal of the De Marco et al.'s study [3] was to evaluate thoracic and lumbar pedicle screws placement to treat a variety of spinal disorders, where these screws were inserted using intra operative anatomical and fluoroscopic parameters.

Daher et al. [4] investigated if the number of pedicular screw (screw density) within the major curve correlates with the curve correction in the surgical treatment of neuromuscular scoliosis and also compared the correction of the major curve

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http://dx.doi.org/10.1016/j.csefa.2015.09.001

and pelvic obliquity using Luque–Galveston instrumentation and pedicle screw constructs in the treatment of neuromuscular scoliosis [5].

Masson et al. [6] had analyzed experimentally the early alterations of the bone-screw interface with tapping techniques in the cancellous bone of the cervical vertebrae.

Vendrame et al. [7] had accessed microscopically bone tissue changes between vertebral bone and implant interface, whose pilot hole was prepared using probe, drill and drill followed by tapping.

A prospective, randomized clinical study was performed by [8] to determine whether unilateral pedicle screw fixation was comparable with bilateral fixation in 1- or 2-segment lumbar interbody fusion.

Other literatures have described typical analysis methods adopted to evaluate materials and failures on pedicle screw.

Chen et al. [9] had investigated the pedicle screw breakage by conducting retrieval analyses of broken pedicle screws from 16 patients clinically and by performing stress analyses in the posterolateral fusion computationally using finite element (FE) models, when fracture surface of screws was studied by scanning electron microscope (SEM).

La Torre et al. [10] had estimated inner forces acting on lumbar spine during activity of lifting objects. After that, using inverse dynamics method the resulting joint between L5/S1 and resulting muscle forces were calculated.

The three basic concepts that are important to the biomechanics of pedicle screw based instrumentation were described by [11], where they are: first, the outer diameter of the screw determines pullout strength, while the inner diameter determines fatigue strength; secondly, when inserting a pedicle screw, the dorsal cortex of the spine should not be violated and the screws on each side should converge and be of good length; and thirdly, fixation can be augmented in cases of severe osteoporosis or revision.

A research done to determine the cause of a broken titanium pedicle screw supporting a prosthesis inserted to repair a broken spinal vertebra in a 38 year old patient was reported by [12].

Siskey et al. [13] had been performed mechanical tests based on the standard ASTM-F1717 protocol, with the exception that displacement control (as opposed to load control) to evaluate the fatigue performance of PEEK spinal fusion rod systems.

Yust [14] had compared a clinically applicable method of testing pedicle screw failure in human cadaver osteoporotic vertebrae to previously studied synthetic bone.

Chang [15] presented a short description about stages of a mechanical failure analysis of a broken bolt, highlighting these stages: (1) character; (2) setting; (3) plot; and (4) conflict.

Fakhouri et al. [16] had compared, using photoelasticity, internal stress produced by USS II type screw with 5.2 and 6.2 mm external diameters, when submitted to three different pullout strengths.

Kueny et al. [17] had determined the fixation strength of three current osteoporotic fixation techniques and had investigated whether or not pullout testing results can directly relate to those of the more physiologic fatigue testing.

In Williams and Chawla [18], fractography of a failed Profemur Z implant showed that a life limiting fatigue crack was nucleated on the anterolateral surface of the implant(tm)s neck.

In Cetin et al. [19], effects of the pedicle screws angled fixation to the rod on the mechanical properties of fixation were investigated.

2. Case history

In what follows the real facts occurred are given a short description:

1. The patient was interned in a local hospital in June 4th, 2009, going through a clinical and physiotherapeutic treatment, being discharged (with no complains) on June 6th, 2009.
2. Returning to the hospital with increasing pains in lumbar spine and taking into account X-rays in the region of L4 and L5 vertebra, a decision was made to proceed to implant a prosthetics to stabilize that region. Standard surgical procedure was performed fixing Titanium Ti6Al4V alloy screws supporting a Titanium connecting bar in two adjacent vertebra. Material was provided by a local vendor, utilizing screws and other necessary parts produced by an international company in June 17th, 2009.
3. A post-surgical radiography, in August 1st, 2009, indicated a correct positioning of screws and connecting bars.
4. After about six months from surgical procedure, in view of new complains by the patient, a new radiography in the lumbar region, showed two fractured screws and a connecting bar, as shown in the following case study report.
5. After this finding, a new radiographic analysis showed the presence of degenerative spondylopathy: degeneration of lumbar vertebra, commonly known as "parrot's beak" in local non-technical language.
6. In March 1st, 2010, a new radiography showed the evidence of Laminectomy, a surgical procedure for the extraction of one or two vertebral lamina, a procedure, we believe, necessary in case of long time exposure of bone marrow.
7. In March 17th, 2010, a new radiography revealed the presence of Retrolistesis, that is, a back dislocation of L4 vertebra over L5 vertebra, a phenomenon affecting seriously the quality of life of the patient.
8. Afterwards, a new analysis showed a Motion Limitation of Lumbar Extension, accelerating the necessity of new surgery to introduce a new prosthetics, which was done in September 9th, 2010, that is, a little over seven months after the first surgery. Radiographies indicated the correct positioning and stability of the new prosthetics.
9. Following a suite of the patient against the vendor of the implant material, the international company responsible for the production of screws and connecting bars, informed very clearly that "the rupture of screws in spinal implants are very

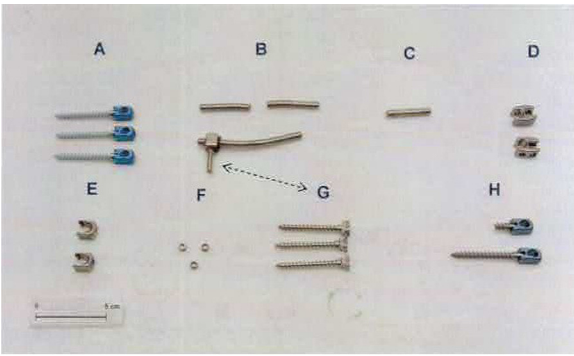

Fig. 1. Materials collected for analysis and evaluation (scale: 5 cm). (A) Three new headless screws; relevant parts: (B) connecting bar, broken in two parts; (C) two small fixation bars; (D) two bars fastening heads; (E) two screws fastening heads; (F) three screws fastening nuts; (G) broken screw attached to broken connecting bar; (H) broken screw [26].

common", what, in reality, does not agree with scientific articles reported [13,20–25] where it is informed that the screws rupture in dorsal implants have an incidence of about 2%. On the other hand, such articles state that this low frequency takes into account a correct surgical technique.

3. Materials and methods

3.1. Materials

After removal and before a new surgical intervention, material extracted from the patient lumbar spine were collected and stored in vacuum and sterile bags for a future evaluation and diagnosis. These materials are shown in Fig. 1.

3.2. Methods

Materials were subjected for chemical analysis, metallographic analysis, chemical treatment, all parts analyzed with modern techniques and instruments [27].

General properties and chemical composition of Ti-6Al-4V are clearly described by [28].

Techniques for cutting of metallographic samples, imbedding, smoothing and polishing obtained from LAMPLAN Co. [29] were used.

Chemical treatment by electrolytic immersion followed the article by [30] and optical and stereoscopic microscopy was performed following a technique similar to the one described by [31], Vickers micro hardness results were compared by values obtained by [32] using Model FM 7 – Future Tech, Micro Hardness Instrument Calibration. Procedures for images analysis are described in [33]. Scanning Electron Microscopy (SEM) techniques and related questions, as given in [34], were adopted.

4. Tests and analysis

Results from the analysis and tests show with high probability, which were the causes of the rupture of the screw and connecting bar while in function after the first surgical intervention.

In what follows we comment on these findings.

4.1. Hardness

Hardness (Table 1) and metallographic essays of the broken and new pieces show no anomalies of the informed Ti-6Al-4V alloy used in the production of these pieces, with α and β phases compatible with the function they were supposed to perform.

Table 1
Micro-hardness Vickers measured in screws normal sections – Load 0.1 Newton [26].

Sample	Vickers hardness (HV)	Uncertainty (HV)[a]
Integral headless screw	350	±38
Broken headless screw	336	±31

[a] According to BS EN ISO 6507-1; 2005 – metallic materials – Vickers hardness test – Part 1: test.

Fig. 2. View of the fracture surface of broken screw [26].

Fig. 2 shows, clearly and without any doubt, that the pedicle screw utilized in the surgical procedure, ruptured by fatigue under alternate flexure, with several points of origin of the fatigue process, under low level of nominal stress. That is, the broken screw showed low resistance to fatigue. Electronic microscopy of this same area validates this hypothesis. About this we shall comment later in this work.

The fractographic analysis shown by Figs. 3 and 4 simply confirm the results of the electronic microscopy.

4.2. Chemical analysis

Chemical analysis shows conformity of the alloy for implant utilization, the same being verified by the samples hardness, with no significant difference between the broken (fatigue) and unbroken screw. No metallographic differences between these screws (Table 2) as seen in Fig. 5, where microstructure comprises globular $\beta-$phase globular particles (dark areas) imbedded in $\alpha-$phase matrix (clear areas). Visual analysis of the broken screw shows plane fracture close to the fourth thread from the screw head. In other words, brittle part was apart from the screw head, something to be noted later on this report.

Chemical analysis is described in Appendix A.

4.3. Stereoscopic analysis

In what concern the stereoscopic analysis, commenting Fig. 6 are seen "beach marks" (white arrows) and multiple fracture origin point (black arrows), characteristic of fatigue fracture in alternate flexion, (A) and (B) fatigue cracks and (C) screw final rupture point.

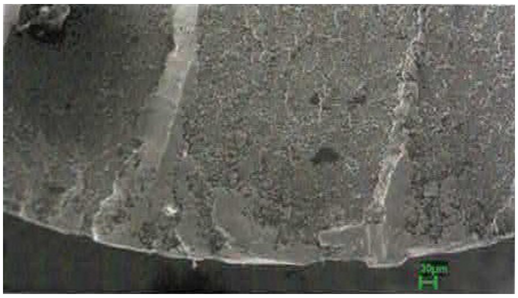

Fig. 3. Fractography – ratched marks are observed at the fracture initial points [26]

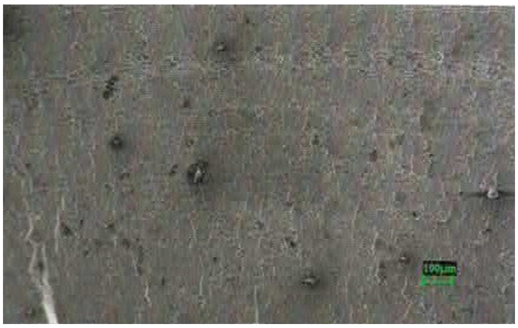

Fig. 4. Fractography – "beach marks" are observed in the region of cracks propagation [26].

Table 2
β–phase percentage [26]

Sample	% β	Standard deviation
Integral headless screw	24	± 1
Broken headless screw	25	± 1

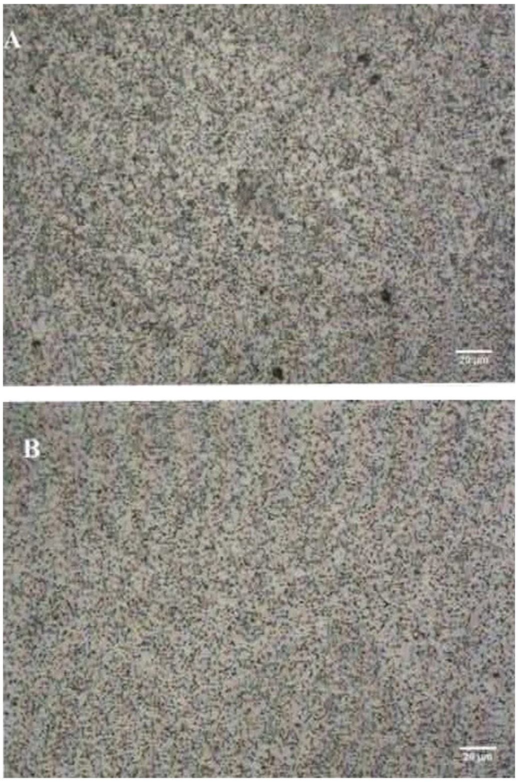

Fig. 5. Metallographic analysis of headless broken screws, normal section: (A) headless integral screw and (B) headless broken screw [26].

Machining scratches are clearly noted in the thread surface. Is a well-known fact that machining scratches and regions with very sharp angles are regions of stress concentration in mechanical parts, causing not few accidents, including airplanes [2,16,35,36]. This is confirmed by a simple analysis of Fig. 7 and 8, where ratched marks and coarse machining scratches are observed.

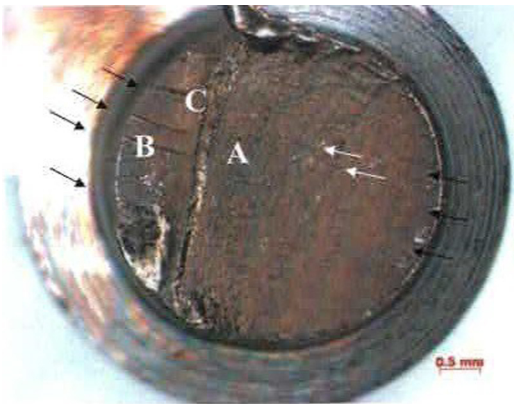

Fig. 6. Stereoscopy. Broken screw fracture surface: (A) and (B) fatigue cracks and (C) screw final rupture point [26].

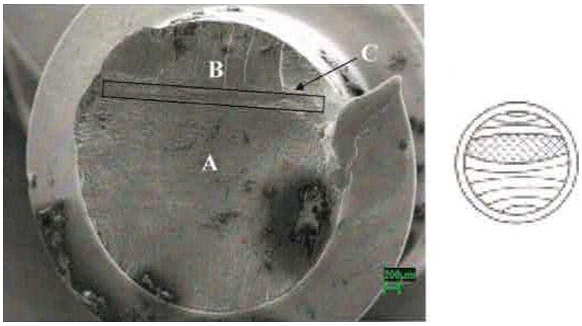

Fig. 7. Fractography. Headless screw fracture surface [26].

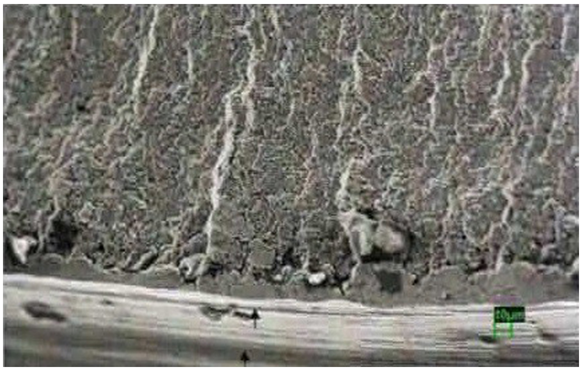

Fig. 8. Fractography. Detail of a point of fracture origin [26].

In Fig. 7, "beach marks" are observed as well as multiple points of fatigue origin. (A) and (B) are fatigue cracks and (C) the region of final fracture, shown in the detail (C). The figure on the right show a pattern of fatigue fracture generated by alternate flexion in low level nominal stress [24].

In Fig. 8 are shown ratched marks and machining scratches. These were relevant facts for the conclusion of the present case. In fact, SEM analyses of the screw lateral surface close to the fracture region, reveal the presence of rough machining scratches. It was obvious that the screw presented stress concentration regions, where fatigue rupture initiated. These regions where produced in the screw machining process, with no relation with the following prosthetics utilization by the patient.

Figs. 9, 10 and 13 serve as a clear confirmation of the above reasoning, stressing the hypothesis of a poor machining process. In Fig. 10 it is relevant the fatigue crack close to a coarse machining scratch (black arrows). Figs. 11 and 12 show secondary cracks in the broken screw, showing its fragility in several regions.

Fig. 9. SEM analysis. Coarse machining scratches parallel to threads and presence of a secondary crack (arrow) [26].

Fig. 10. Secondary crack shown in Fig. 9, identified by a white arrow [26].

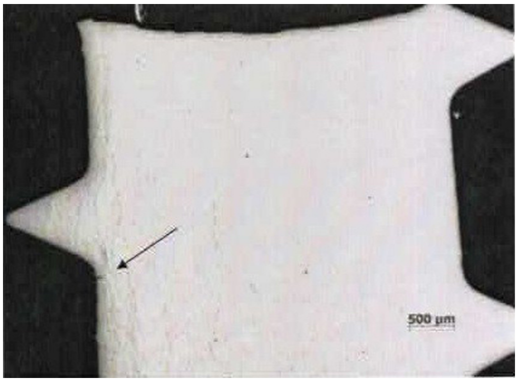

Fig. 11. Metallography. Section normal to fracture. Noticeable is a crack at the root of a thread (arrow) [26].

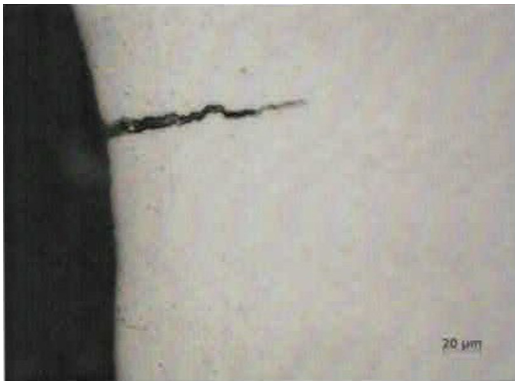

Fig. 12. Metallography. Detail of crack observed in Fig. 11 [26].

4.4. Second stage of analyses

A second stage of the analyses and tests dealt with the rupture of a connecting bar serving as a stabilization bridge between the pedicle screws on each side of the vertebra. Chemical and metallographic analyses of the broken bar and the integral bar show no sensible difference and their conformity for the proposed utilization. The integral bar show a large curvature, eventually necessary for the correct positioning of the bar and screws kit. No information was available about how many flexures where necessary for the prosthetics correct positioning. The rupture of the connecting bar shows a unidirectional flexure or stress. This seems to indicate that the bar fracture could initiate before the implant procedure since, on the contrary, we suppose, a bidirectional flexure should be observed. Such fact could be related with the technique used to adjust the bar curvature until the correct value was achieved, a difficult point to be analyzed. On the other and Fig. 14 shows that the fatigue fracture initiated in a ratched marks region at the bar surface. The question raised at this point was the cause

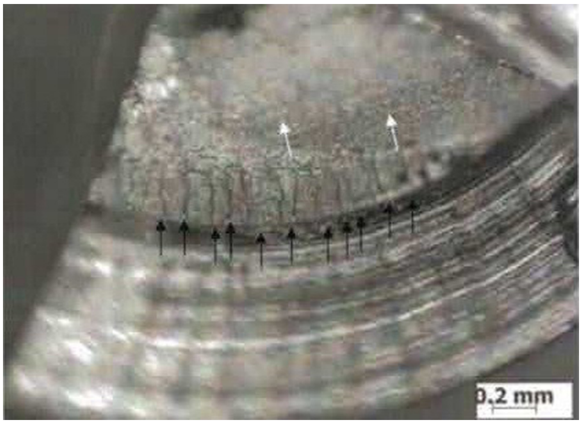

Fig. 13. Stereoscopy. Crack shown is Fig. 12 after cutting a normal section [26].

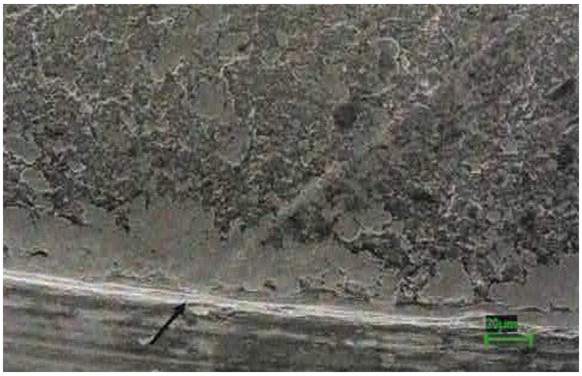

Fig. 14. Ratched marks in the region of fracture origin [26].

of this ratched mark, since with high probability the fatigue crack started at this point and propagated along the entire broken section.

Besides all points above analyzed, the same situation is observed as per the broken screw as shown by Fig. 15: machining scratches close to the original fracture point.

Another important information was given by Fig. 16, where it is seen that ratched marks and stain cover the fatigue fracture cracks.

It is a well-known fact that oxidation decreases the resistance of titanium–aluminum alloys prosthetics [37–39]. More important is Fig. 17, showing fatigue cracks at broken bar threads roots.

With no doubts, these areas are stress concentration regions, possibly resulting from an excessive acute angle of the thread during the machining process. It is important to note that integral bar threads roots show a smooth angle, in favor of stress concentration absence. Is it possible to have geometric difference between the broken and integral bars? This surely depends on the geometry of the tool used to cut the bar threads, which could be the result of wear of such tools.

Fig. 18 clearly shows the fatigue crack progress from the broken bar threads roots.

In this enlarged image, a plastic deformation is clearly visible, at the thread roots with material rupture. Starting from initial cracks a propagation o fatigue cracks is observed. On the other hand, the integral bar shows no presence of fatigue or any other type of crack. An interesting open question is that if similar mechanical load was acted on both connecting bars, why the integral bar showed no fatigue cracks, of any size. It possible that the surgical method used might explain such difference, something out the scope of this work.

With respect to the remaining components (Fig. 19), nothing was to be reported, although the fact that they play an important role in the prosthetic structure.

In the laboratory report it should be stressed the following note: in the broken headless screw the fatigue fracture and secondary crack process are associated to coarse machining scratches, noted at the root of the screws threads. In case of the fractured bar the fatigue fracture might have been facilitated by an excessive load (by bending or stressing) generating fatigue micro-cracks at the threads roots. No information was available about the manual process used to adjust the bar curvature to be adapted for the prosthetics implant.

Under these conditions, excluding the possibility of improper surgical procedure, the conclusions are listed as follows.

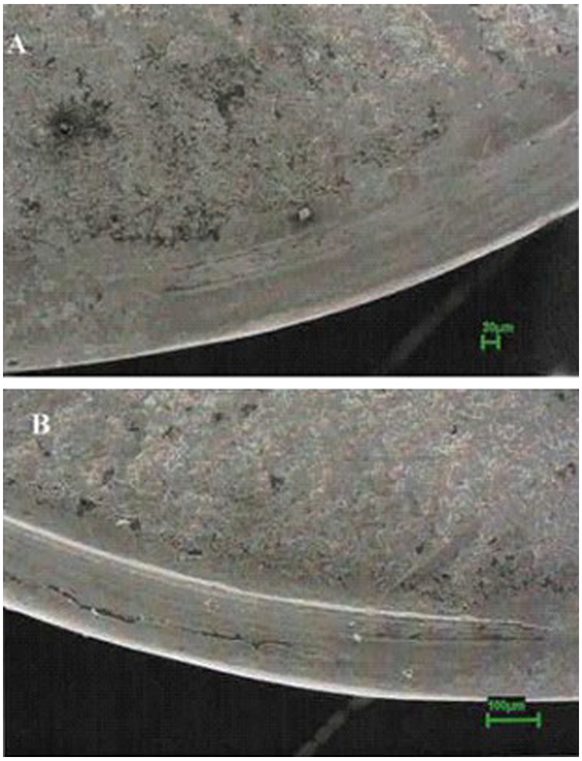

Fig. 15. Machining scratches close to the fracture origin [26].

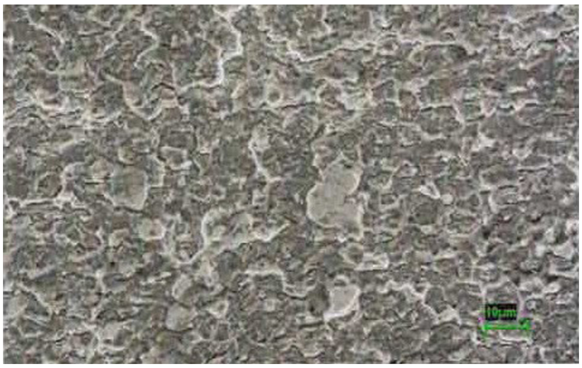

Fig. 16. Scratches in a region far from fracture origin, ratched marks and oxidation disguise secondary scratches [26].

5. Discussions

The analysis performed in Section 4 of this work, lead to the following conclusions:

- Titanium alloy used in the production of all pieces under analysis was totally adequate for application in dorsal implants, according to current standards [40].
- The presence of coarse scratches resulting from the machining process both in the screws and the connecting bar certainly was the origin of fatigue cracks leading to the failure of these components.
- The bar repeating bending before positioning might have been an additional factor facilitating the fatigue rupture of the connecting bar. On the other hand the scratches produced by the machining process, the excessive acute angles in the threads and the observed ratched marks surely contributed to a low fatigue resistance of the connecting bar.
- In view of the foregoing analyses, it was discarded the idea of fatigue test in new pedicle screws. In fact a kit of the same family that the one used to implant the prosthetics was not available and a fatigue test on these new pieces would not lead

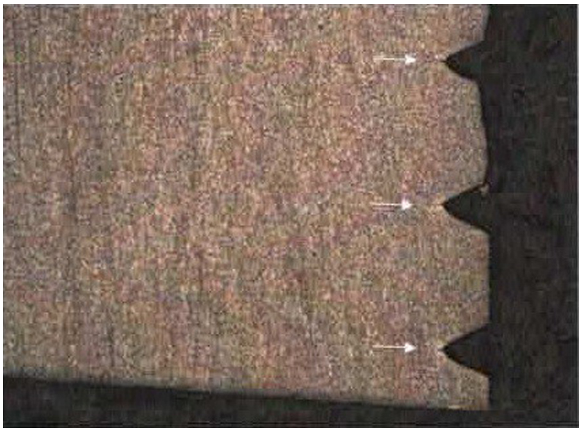

Fig. 17. Metallographic analysis. Broken connecting bar, longitudinal section. Cracks at the thread roots (arrows) are seen [26].

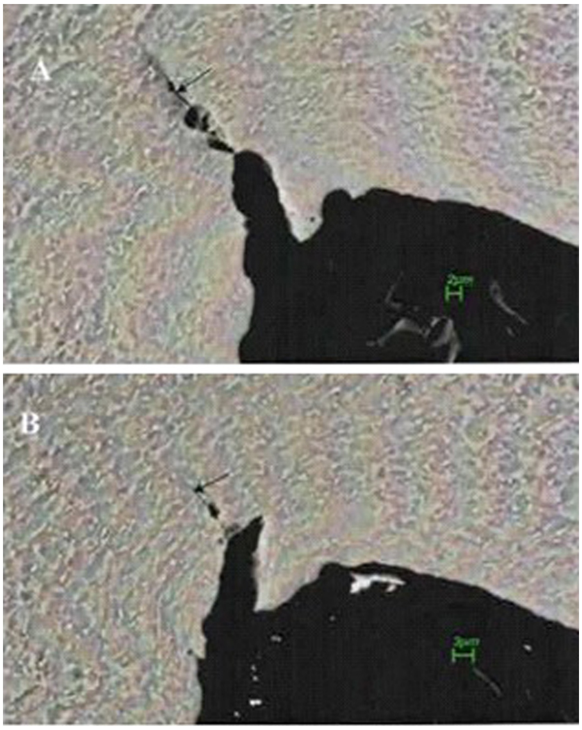

Fig. 18. SEM analysis, broken connecting bar longitudinal section [26].

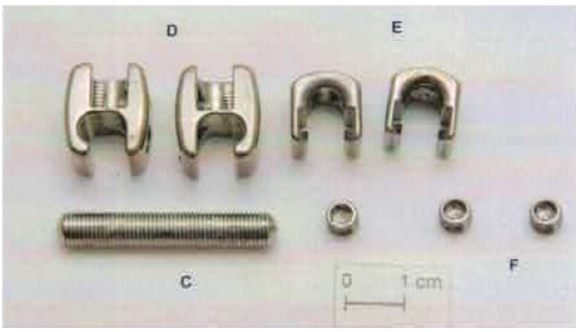

Fig. 19. Visual examination of other parts of prosthetics show no failure [26].

to a useful conclusion. The machining process certainly presents small but important variations, especially when dealing with Titanium alloys.

It was concluded that the connecting bar collapsed under fatigue. From a structural point of view, the best hypothesis is that the headless screw collapsed first, causing an anomalous stress upon the connecting bar still attached to the adjacent headless screw and subjected to an excess stress caused by the vertebra movements. In case the connecting bar had failed before the screw, there resulted a small or even null on the screw remaining simply attached to the vertebra, under no stress.

6. Conclusions

Excluding an incorrect prosthesis implantation in the surgical procedure and a possible low bone density, an information not available to the research team, with high probability the rupture of metallic pieces used in the prosthetic implant, was produced by the low fatigue resistance resulting by an improper machining process and excessive bending of the connecting bar prior to implant.

Acknowledgements

Dr. Wendell de Queiroz Lamas thanks his "Productivity Scholarship in Research," supported by the Brazilian National Council for Scientific and Technological Development (CNPq), grant number 301260/2013-3.

Appendix A

The percentages of analyzed elements are shown in Table 3 and are in accordance with the Ti-6Al-4V alloy according to standard ASTM F 136-02a.

Note: Chemical analyses were compared with Certified NIST 173c material. The uncertainty in results are declared with standard uncertainty multiplied by factor $k = 2$, which gives a reliability level of about 95%.

Table 3
Chemical analyses of samples as specified [26].

Element	New screw	Large broken bar	Large unbroken bar	Headless unbroken screw	Headless broken screw
Al	6.38 ± 0.11	6.34 ± 0.12	6.81 ± 0.12	6.67 ± 0.15	6.21 ± 0.12
V	4.17 ± 0.07	4.05 ± 0.07	4.13 ± 0.07	4.10 ± 0.09	4.09 ± 0.07
Fe	0.05 ± 0.01	0.17 ± 0.01	0.17 ± 0.01	0.22 ± 0.01	0.05 ± 0.01
Cu	0.004 ± 0.009	0.004 ± 0.009	0.004 ± 0.009	0.004 ± 0.009	<0.0021
Ni	0.013 ± 0.002	0.012 ± 0.002	0.012 ± 0.002	0.018 ± 0.002	0.013 ± 0.002
Cr	0.016 ± 0.018	0.012 ± 0.018	0.011 ± 0.018	0.013 ± 0.018	0.012 ± 0.018
C	0.016 ± 0.006	0.033 ± 0.006	0.020 ± 0.006	0.020 ± 0.006	0.030 ± 0.006
O	0.096 ± 0.003	0.115 ± 0.002	0.124 ± 0.006	0.114 ± 0.000	0.110 ± 0.011
N	0.002 ± 0.000	0.007 ± 0.001	0.006 ± 0.000	0.006 ± 0.000	0.005 ± 0.001

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